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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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01/09/2004

Leslie Joe Dunaway

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EXAMINER

HUYNH, CARLIC K

ART UNIT

PAPER NUMBER

1612

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/755,125	<b>Applicant(s)</b> DUNAWAY, LESLIE JOE	
	<b>Examiner</b> CARLIC K. HUYNH	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-15, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 16-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of applicants' amendments and remarks filed on November 30, 2007 is acknowledged.

#### ***Status of the Claims***

1. Claims 1-26 are pending in the application, with claims 7-15 and 25-26 having been withdrawn in a response to the restriction requirement filed on June 20, 2007. Accordingly, claims 1-6 and 16-24 are being examined on the merits herein.

#### ***Specification***

2. The use of the trademarks Singulair®, Zivirax®, and Famvir® was noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

#### ***Response to Arguments***

3. Applicants' amendments, see "Remarks" filed on November 30, 2007, with respect to "Specification" for use of registered trademarks have been fully considered and are found not persuasive. Applicants have amended the specification by adding the word "medication" following each instance of the registered trademark "Singulair®". The addition of "medication"

following “Singulair®” does not meet the requirement to capitalize registered trademarks accompanied by the generic terminology. Thus the objection to the specification for use of registered trademarks has been maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLong et al. (US 2006/0247214) as evidenced by O’Byrne (Chest, 1997, Vol.111, No. 2 Supplement, pp 27S-34S), in view of Pizzichini et al. (European Respiratory Journal, 1999, Vol. 14, pp. 12-18) as evidenced by SINGULAIR® product information (Merck & Co, Inc., April 2007, pp. 1-19).

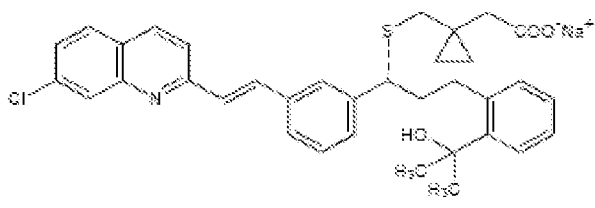
DeLong et al. teach a method for reversing hair graying in mammals comprising administering nonsteroidal anti-inflammatories such as cyclooxygenase or lipoxygenase inhibitors (page 13, paragraph [0110]; and page 14, paragraph [0131]).

As evidenced by O’Byrne, lipoxygenase inhibitors block the production of leukotrienes as a means to control allergic and inflammatory diseases such as asthma (abstract and page 28S, figure 1). Thus, the inhibition of leukotrienes may be used to reduce the inflammatory response.

DeLong et al. do not teach 1-(((1(R-(3-(2-(7-chloro-2-quinoliny)ethenyl)phenyl)-3-(2-(2-hydroxy-2-propyl)phenyl)propyl)thio)methyl) cyclopropaneacetic acid.

Pizzichini et al. teach a cyteinyl leukotriene<sub>1</sub> (CysLT<sub>1</sub>) receptor antagonist, montelukast, can be used to treat allergic and inflammatory diseases such as asthma (abstract). Thus the inflammatory response may be reduced by using antagonists to leukotrienes.

As evidenced by SINGULAIR® product information from Merck & Co, Inc., montelukast has the chemical formula of,



and has the chemical name of 1-(((1(R-(3-(2-(7-chloro-2-quinolinyl)ethenyl)phenyl)-3-(2-(2-hydroxy-2-propyl)phenyl)propyl)thio)methyl) cyclopropaneacetic acid, which is the same compound as the elected compound of 1-(((1(R-(3-(2-(7-chloro-2-quinolinyl)ethenyl)phenyl)-3-(2-(2-hydroxy-2-propyl)phenyl)propyl)thio)methyl) cyclopropaneacetic acid (page 1).

Since DeLong et al. teach lipoxygenase inhibitors that control an inflammatory condition such as asthma can also be used to reverse hair graying, and since Pizzichini et al. teach the leukotriene antagonist montelukast can control an inflammatory condition such as asthma, it would obvious to one in the art that montelukast can also be used to reverse hair graying.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the lipoxygase inhibitor composition of DeLong et al. to contain montelukast because the compound of Pizzichini et al. is montelukast and according to Pizzichini et al., montelukast can be used to control asthma and thus reverse hair graying.

The motivation to combine the lipxygenase composition of DeLong et al. to the montelukast composition of Pizzichini et al. is that Pizzichini et al. teach montelukast can be used to control asthma and thus reverse hair graying.

It is noted that “It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose” and “It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose”. *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

### ***Response to Arguments***

5. Applicants’ arguments, see “Remarks” filed on November 30, 2007, with respect to “Rejections under 35 U.S.C. § 103” to claims 1-6 and 16-24 have been fully considered and are not found persuasive.

Applicants argue that DeLong et al. (US 2006/0247214) teach prostaglandins, not any optional anti-inflammatory ingredient such as the lipxygenase inhibitor montelukast, prevents graying of hair. Moreover, Applicants argue that DeLong et al. state that the anti-graying characteristic is universal to any number of the compounds taught by DeLong et al., suggesting that the prostaglandin component is responsible for the anti-graying effect.

Applicants further argue that the montelukast composition is an oral pharmaceutical while the DeLong et al. composition is a topical product.

Applicants also argue that DeLong et al. refer to reversing the gray coloring of hair rather than inhibiting hair graying.

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Regarding the DeLong et al. reference, Examiner maintains and points out that DeLong et al. teach a method for reversing hair graying in mammals comprising administering nonsteroidal anti-inflammatories such as cyclooxygenase or lipoxygenase inhibitors (page 13, paragraph [0110]; and page 14, paragraph [0131]). Moreover, Applicants have admitted that in paragraph [0156] of DeLong et al. suggest that the anti-graying characteristic is universal to any number of the compounds taught in DeLong et al.

O'Byrne (Chest, 1997, Vol.111, No. 2 Supplement, pp 27S-34S) was used solely to show that lipoxygenase inhibitors block leukotriene production and can treat asthma (abstract and figure 1). Pizzichini et al. (European Respiratory Journal, 1999, Vol. 14, pp. 12-18) teach a leukotriene receptor antagonist, montelukast, can be used to treat asthma. The SINGULAIR® product information from Merck & Co, Inc. is used solely to show that SINGULAIR® (montelukast) is known in the art as 1-(((1(R-(3-(2-(7-chloro-2-quinolinyl)ethenyl)phenyl)-3-(2-(2-hydroxy-2-propyl)phenyl)propyl)thio)methyl) cyclopropaneacetic acid. The motivation to combine DeLong et al. and Pizzichini et al. is that the underlying mechanism of montelukast and lipoxygenase inhibitors is the blockade of leukotriene production.

Regarding the inconsistency of an oral composition of montelukast and the topical composition of DeLong et al., compositions are routinely made into a number of pharmaceutical dosage forms. Thus it would be obvious that a skilled artisan would possess the knowledge to produce a composition for either oral or topical administration.

It is noted that claims 1-6 and 16-24 are directed to treating graying of hair and thus DeLong et al., which teach a method of reversing gray coloring of hair, is properly used. Moreover, inhibiting graying of scalp hair and reversing gray coloring of hair are considered

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methods of treating the graying of hair and thus the method taught in DeLong et al. is properly used.

Thus, the Rejections under 35 U.S.C. § 103 to claims 1-6 and 16-24 have been maintained.

### ***Conclusion***

6. No claims are allowable.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/  
Primary Examiner, Art Unit 1612

ckh